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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,419	08/08/2001	Jamie Rossjohn	3991/OJ678	9005
7278	7590	11/18/2005	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,419

Applicant(s)

ROSSJOHN ET AL.

Examiner

Prema M. Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8,10-34 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) 12-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-6, 8, 10-11, 32-34, 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1646

DETAILED ACTION

1. Claims 3, 7, 9, and 35 have been canceled (10/6/2005). Amended claims 1, 2, 4-6, 8, 10, 11, 33-34 (10/6/2005), and new claims 36-40 (10/6/2005) are under consideration.

2. Receipt of applicant's arguments and amendments filed on 10/6/2005 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 11/10/2005:

(i) the objection to the title; and

(ii) the rejection of claims 1-6, 8, 10-11, 32-35 under 35 U.S.C. 112, second paragraph. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

4. Applicant's arguments filed on 10/6/2005 have been fully considered and were non-persuasive in part. The issues remaining as well as new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 112, first paragraph

6. Claims 1, 32, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1646

Amended claim 1, recites "human" which language is new matter in the claim, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

The specification on pages 12-13, Table 2, discloses amino acids for interaction between D4 β c and BION-1. However, there is no mention in the specification as to the source of the amino acids, which is insufficient description to support the "human" limitation recited in amended claim 1.

Furthermore, there is insufficient description for the limitation "having a surface representation and alignment to a structure" as recited in amended claim 1, lines 7-8.

Amended claim 32 recites "having a spatial configuration according to Figure 1C" which language is new matter in the claim, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

"Besides the ladder, there are three other significant surface features worth noting. There are two large hydrophobic patches on the surface. The first, H1, is a dense strip of hydrophobic residues located at one edge of the β -sandwich defined by the D' and E' strands and measures 27 Å long and 6 Å in width (Fig. 1D). The second, H2, located on the opposite face to the first, forms part of a lip at the end of a pronounced groove on the surface of the molecule (Fig. 1C). The H2 patch is made up of residues Ile 338, Ala 341, Met 361, Tyr 365, and preferably including Met 340 and Pro 342 and the aliphatic moiety of Lys 362 and preferably including Ile 368 and Tyr 421. The groove is located at the N-terminal end of the molecule where one wall is formed by the B'-C'

Art Unit: 1646

loop and part of the F'-G' loop and the other wall by the N-terminus (residues 338 to 342) (Fig. 1C)."

The specification does not disclose the specific limitations recited in amended claims 1, 32. This rejection can only be obviated by reciting the specific limitations for which there are support in the instant specification.

7. Claims 1-2, 4-6, 8, 10, 11, 32-34, 36-40, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth at pages 4-7 of the previous Office action (6/6/2005).

The written description in this case only sets forth the specific residues 338-438 of D4 β_c which residues were expressed using the pEC611 vector in *E. coli* and that an antibody BION-1 MoAb raised against D4 β_c was used to obtain crystals of the antibody and D4 β_c . The written description fails to recite the species source of the residues (see page 21, Example 1, lines 10-20) as well as fails to recite the specific amino acids that make up the "domain consisting of a portion of D4 β_c ...". This is insufficient description to support the claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Applicants argue that the claims have been amended to incorporate the language in the specification. However, contrary to Applicants arguments, the issue here is that the specification fails to recite that the domain being claimed is human or the specific amino acids that form the

Art Unit: 1646

portion of the D4 β c chain of the cytokine receptor. Therefore, Applicants have failed to obviate the standing 35 USC 112, first paragraph, written description rejection over claims 1-2, 4-6, 8, 10-11, 32-34, 36-40.

Claim Rejections - 35 USC § 112, second paragraph

8. Claims 1-2, 4-6, 8, 10-11, 32-34, 36-40, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record set forth at pages 7-8 of the previous Office action (6/6/2005).

Claims 1-2, 4-6, 8, 10-11, 32-34, 36-40 are vague and indefinite because there is no SEQ ID NO recited in the claims. Therefore, with respect to the specific amino acids recited, for example the recitation of Tyr365, His367, Ile368, in claim 1, in the absence of a specific reference amino acid sequence or baseline sequence, it is impossible to determine where these specific amino acids are in the various cytokine receptors. Similarly with respect to claim 2, it is unclear which cytokine receptor the residues 418 and 421 are in? Recitation of these residues in the claim are meaningless in the absence of a reference amino acid sequence. Applicants argue that claim 1 has been amended to recite human cytokine-binding domain of a cytokine receptor. However, contrary to Applicants arguments, the claims remain vague and indefinite because it is unclear which cytokine receptor is being referred to. Furthermore, there will probably not be a Tyrosine at position 421 in all cytokine receptors.

Art Unit: 1646

Claim 1 is vague and indefinite because in line 2 after "Domain 4 of a β c" should be recited "(D4 β c)" in brackets, and this acronym should be consistently recited in all the dependent claims.

Claim 1, lines 6-7, recites the limitation "the N-terminal section". There is insufficient antecedent basis for this limitation in the claim.

Claim 4, is improper because in line 2, "Tyrosine" is capitalized but in line 3 "tyrosine" is not capitalized.

Regarding claim 4, line 2, the term "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim rejections-35 USC § 102

9a. Claims 1-2, 4-6, 10-11, 32-34, 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/07215.

This rejection is maintained for reasons of record set forth at page 9 of the previous Office action (6/6/2005).

Applicants argue that the claims have been amended to recite "a portion of D4 β c said portion defined by a portion of the B'-C' loop of D4Bc and a groove defined by the B'-C', F'-G' loops and the N-terminal section of D4Bc." Applicants also submit that the amendments to the claims, which recite that the claimed structure is "a portion of D4 β c" and distinguish the claimed invention over the prior art. Applicants also argue that "portion" has the common meaning of "a section or quantity within a larger thing". However, contrary to Applicants arguments, in the absence of a definition for "a portion" in the instant specification, "a portion" encompasses the

Art Unit: 1646

entire cytokine-binding domain less a single amino acid at the end of the domain. Furthermore, the metes and bounds of "cytokine-binding domain" are unclear because of the term "comprises" in claim 2, "including" in claim 3 and "or combination thereof" in claim 6, and "comprising/comprises" in claims 32-34, 36-38. Therefore, the reference anticipates claims 1-2, 4-6, 10-11, 32-34, 36-40.

9b. Claims 1-2, 4-6, 10-11, 32-34, 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodcock et al. (1997).

This rejection is maintained for reasons of record set forth at pages 9-10 of the previous Office action (6/6/2005).

Applicants argue that the claims have been amended to recite "a portion of D4 β c said portion defined by a portion of the B'-C' loop of D4Bc and a groove defined by the B'-C', F'-G' loops and the N-terminal section of D4Bc." Applicants also submit that the amendments to the claims, which recite that the claimed structure is "a portion of D4 β c" and distinguish the claimed invention over the prior art. Applicants argue that "portion" has the common meaning of "a section or quantity within a larger thing". Applicants also argue that the reference does not teach the structure of the specific portion of the D4 β c domain. However, contrary to Applicants arguments, in the absence of a definition for "a portion" in the instant specification, "a portion" encompasses the entire cytokine-binding domain less a single amino acid at the end of the domain. Furthermore, the metes and bounds of "cytokine-binding domain" are unclear because of the term "comprises" in claim 2, "including" in claim 3 and "or combination thereof" in claim 6, and "comprising/comprises" in claims 32-34, 36-38. Therefore, the reference anticipates claims 1-2, 4-6, 10-11, 32-34, 36-40.

Art Unit: 1646

Conclusion

No claim is allowed.

Claims 1-2, 4-6, 8, 10-11, 32-34, 36-40 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1646

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
October 26, 2005